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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,739	07/28/2003	Gila Maor	26243	4122

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EXAMINER	
LANKFORD JR, LEON B	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,739	MAOR, GILA	
	Examiner	Art Unit	
	Leon Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon reconsideration and in view of applicant's arguments, a new restriction requirement is made herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23 & 104-107, drawn to a method of culturing chondrocytes, classified in class 435, subclass 325.

II. Claims 45-59, drawn to a method of redifferentiating dedifferentiated chondrocytes, classified in class 435, subclass 377.

III. Claims 60-62, drawn to isolated mandibular condyle tissue, classified in class 623, subclass 23.72.

IV. Claims 63-79, drawn to a cell culture comprising isolate chondrocytes, classified in class 435, subclass 366.

V. Claims 80-103, drawn to a method of treating cartilage or bone disease in a subject, classified in class 424, subclass 93.7.

VI. Claims 24-44, drawn to a method of forming bone from chondrocytes from mandibular tissue, classified in class 435, subclass 378.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, V, and VI are each distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent

on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the method of invention I requires isolation of chondrocytes from mandibular condyle tissue and culturing the chondrocytes. The method of invention I differs from the method of invention II because the methods require different starting populations of chondrocytes. Specifically, the method of invention I requires chondrocytes to be isolated directly from the mandibular tissue, these cells are not dedifferentiated and no steps are required to redifferentiate the chondrocytes; alternatively, the method of invention II does not require the chondrocytes to be isolated from the mandibular condyle tissue, but rather requires the starting chondrocytes to be dedifferentiated chondrocytes and requires additional steps to redifferentiate the cells. The method of invention VI is distinct from each of the methods of inventions I and II because the method of invention VI is intended to form bone from isolated chondrocytes from mandibular condyle tissue, thus it has a different effect than either of the culture methods of inventions I and II and one need not practice one method in order to practice the others. Method VI appears to require components specifically excluded from invention I. It is further noted that the method of invention II does not even require the chondrocytes to be isolated from the mandibular condyle tissue. The method of invention V is distinct from the methods of inventions I, II and VI because it has a different effect, as it is intended to treat bone disease in a subject, and does not require any of the methods of inventions I, II, or VI. The chondrocytes used in invention V can alternatively be harvested from other areas, such as cartilage in the

knee, and thus the method of invention V does not need to be practiced in coordination with the other methods.

Invention III is related to inventions I, II, V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the isolated mandibular condyle tissue is determined to be the product, and the methods of inventions I, II, V, and VI can make use of the chondrocytes isolated from the tissue; however, the isolated mandibular condyle tissue of invention III is not intrinsically linked to any one of the methods of inventions I, II, V or VI, as the isolated tissue could alternatively be used as a cell scaffold for the three-dimensional culture of chondrocytes and/or bone cells for the production of cartilage and/or bone replacements.

Invention IV is related to inventions I, II and VI as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cell culture of invention IV is determined to be the product and inventions I, II and VI define different ways to make the product. However, the product of invention IV is determined to not be intrinsically linked to any one of the methods of inventions I, II or VI, because the

cell culture product of invention IV can be produced by a method distinct from any of said methods, for example, a cell culture such as that of invention IV can be produced by isolating fully differentiated chondrocyte cells from cartilage in the knee and cultured in vitro. None of the methods of inventions I, II or VI require isolation of fully differentiated chondrocytes from tissue other than mandibular condyle tissue.

Invention IV is related to inventions V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the cell culture of invention IV is determined to be the product, and the method of invention V defines a method of using the cell culture product; however, the cell culture comprising isolated chondrocytes of invention IV is not intrinsically linked to the method of invention V because the cell culture can alternatively be used for in vitro drug toxicity testing instead of implantation into a subject. Therefore, the product has other uses besides that of invention V.

Inventions III and IV are distinct inventions and thus are subject to restriction. The inventions are distinct in that the products are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the isolated mandibular condyle tissue of invention III can be used for implantation and or in vitro testing; thus it has functions besides that of supplying

chondrocytes for cell culture. Alternatively, the isolated cell culture of invention IV can be derived from tissue other than mandibular condyle tissue. Therefore, the products do not rely on one another, they be produced and used separately and thus restriction is proper.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai, In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to the following patentably distinct species: each of inventions I-VI require certain distinct chemical components which makes teach species of the claimed invention thus distinct. The species are independent or distinct because they are chemically different and different in function.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

For Group I-VI, the specific supplements (not generic) used in the media must be elected, e.g. from claims 14, 33, 37 or 49.

Currently, the first claim from each grouped invention is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are

added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford Jr
Primary Examiner
Art Unit 1651